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August 15, 2003

Marianne L. Horinko, Acting Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the HPV Test Plan for the Mononitroanilines category

Dear Administrator Horinko:

The following comments on the Solutia Inc (Solutia) test plan for the Mononitroanilines category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Solutia submitted its test plan on April 9, 2003 for the chemicals 2-nitro-Benzeneamine (ONA, CAS No. 88-74-4) and 4-nitro-Benzeneamine (PNA, CAS No. 100-01-6). The major uses and hazards are well characterized for these chemicals in the test plan, and a concise and complete description is given for the required endpoints. This two-chemical category is justified by structural and behavioral similarities as well as similarities in physicochemical properties and ecological and mammalian toxicity measures. Most of the OECD SIDS data endpoints required by the program have already been fulfilled, and other data is available in published sources, so it follows that Solutia proposes no new tests. Although reproductive toxicity data is not available for ONA, it can be completed by category read-across, a negative developmental study and negative reproductive organ histopathology from repeat-dose studies. Furthermore, key acute and repeat-dose studies given to fulfill necessary endpoints are properly chosen, as primary occupational exposures occur through inhalation and dermal routes. Solutia has conducted a thoughtful analysis of the data, and summarized this in a clear and concise manner.

We applaud Solutia's efforts at ensuring all available information is provided for the nitroanilines and concur that no additional animal testing is necessary under the HPV Challenge Program. This approach is consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to toxicology. Thank you for your attention to these

comments. I may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org.

Sincerely,

Kristie M Stoick, M.P.H.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research